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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,348	03/24/2005	Ilan Shalev	331/04204	5391

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,348	SHALEV, ILAN	
	Examiner	Art Unit	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *16-18,25,36-38 and 40-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,19-24,26-35,39 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/27/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of species I in the reply filed on August 10, 2006 is acknowledged.

2. Claims 16-18, 25, 36-38, and 40-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 10, 2006. Claims 36-38 were previously indicated as being generic claims. However, in reviewing the claims, it has been determined that claims 36-38 read on non-elected species II which is shown in Figures 3 and 4 and which is described in lines 29-31 of page 17 of the specification.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the hollow tube defining at least one aperture, which comprises at least one front opening at a front end of the tube and at least one side opening in a side of the tube, must be shown or the feature(s) canceled from the claim(s). Also, the hollow tube defining at least one aperture, which is covered by at least one extension in the first position, must be shown or the feature(s) canceled from the claim(s). Also, the positions being axially displaced and radially displaced must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. Figures 1A – 1F should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "110" has been used to designate both a stand in Figure 1F and a bore in Figures 2C and 2D and reference character "134" has been used to designate both an inlet and an extension in Figure 5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 128, 210. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities: The paragraphs in lines 3-5 of page 4 and in lines 14-15 of page 20 are unclear. Reference character 316 has been used for a skin flat in line 5 of page 18 and for a sheath in line 19 of page 18. Appropriate correction is required.

Claim Objections

8. Claims 2-10, 14, 15, 20-24, 26-35, 39, 44, and 45 are objected to because of the following informalities: Claims 2-4 recite the limitation "said aperture" in line 1. Claims 5-9 recite the limitation "said impediment" in line 1. Claim 10 recites the limitation "said body tissue" in line 1. Claims 14, 15, 44, and 45 recite the limitation "said extensions" in line 2. Claim 20 recites the limitation "the activating mechanism" in line 1. Claims 21-23 recite the limitations "said extending", "said extensions", and "said intake of fluid" in lines 1 and 2. Claim 24 recites the limitation "said extension" in line 2. Claim 26 recites the limitation "said one or more extensions" in line 2. Claim 27 recites the limitation "said apertures" in line 1. Claim 28 recites the limitations "said catheter" in lines 1 and 2, "said extensions" in line 2, and "said body fluid" in line 3. Claims 29-31 recite the limitations "said catheter" in lines 1 and 2 and "said extensions" in line 2. Claims 32 and 39 recite the limitation "the one of more extensions" in line 1. Claim 33 recites the

limitation "said one or more expandable elements" in line 1. Claim 34 recites the limitation "said one or more expandable element extensions" in lines 2 and 3. Claim 35 recites the limitation "said expandable element" in lines 2 and 3. There is insufficient antecedent basis for these limitations in these claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-7, 9-15, 19, 21-24, 27-34, 39, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan et al (U.S. Patent No. 5,609,574). In Figures 1 and 1E, Kaplan et al show an apparatus or device comprising a hollow tube (20) with apertures (22 and 34), expandable resilient extensions (28 and 32), and an activating mechanism (40). The extension is operative in a deflated or first position and an inflated or second position by the manual activation of the activating mechanism. The activating mechanism includes a reservoir containing expansion fluid which is used to expand the extension. In the first position, the extension is near the aperture (22). In

the second position, at least part of the extension extends away from the aperture. Figure 6 shows the hollow tubes with additional apertures (34). As to claims 5-7, 9, and 10, in Figures 8A, 8B, and 17A – 17D, an impediment (S) in the form of an aggregate of solid material or inflamed body tissue which is located down flow from the hollow tube or at least partly within the hollow tube is shown. In lines 46-56 of column 13, Kaplan et al disclose that an agent or impediment may be located partly within the hollow tube. As to claims 11 and 12, Kaplan et al teach that the device may be left in a the patient's body between treatments (lines 1-10, column 17) and disclose the claimed structural elements of the device, thus, the device of Kaplan et al is capable of being implanted in a patient's vein for a period of one or more weeks and/or months. As to claims 21-24, Kaplan et al teach that the delivery of the fluid may be performed before, after, or during the inflation of the extension (lines 18-31, column 16). As to claim 27, the apertures in Figure 6 would be covered by the wall tissue of a patient's vein as the device is advanced in a deflated configuration through the narrow passages of the patient's body. As to claims 28-31, Kaplan et al disclose the tube comprising or having a material or fluid which is delivered into the particular portions of a patient's body which include fluids which are capable of preventing aggregation of solids, clot formation, body tissue inflammatory response, and bacteria colonization (see lines 53-67 of column 9 and lines 36-49 of column 11). As to claims 44 and 45, Kaplan et al teach that the device may be adapted for veins, arteries, and other locations in a patient's body and disclose the claimed structural elements of the device, thus, the device of Kaplan et al is capable of being adapted for an arm vein and fro an non-vein vessel. As to claims 46 and 47, at

least a part of the extension is axially displaced when it is in the inflated position and at least a part of the extension is radially displaced when it is in the inflated position.

11. Claims 1, 3, 5-7, 9-15, 19-24, 26-35, 39, and 44-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Zadno-Azizi (U.S. Patent No. 6,958,059). In Figures 12 and 13, Zadno-Azizi shows an apparatus or device comprising a hollow tube (14, 420) with apertures (240, 460), a resilient expandable extension (12, 422), and an activating mechanism. The extension is operative in a deflated or first position and an inflated or second position by the automatic activation of the activating mechanism (see lines 9-32 of column 6). The activation can also be considered to be partly manual (rotation of the knob). The activating mechanism includes a reservoir containing expansion fluid which is used to expand the extension. In the first position, the extension is near an aperture. In the second position, at least part of the extension extends away from the aperture. As to claims 5-7, 9, and 10, in Figures 9A and 9B, an impediment (S) in the form of an aggregate of solid material or inflamed body tissue which is located down flow from the hollow tube or at least partly within the hollow tube is shown. As to claims 11 and 12, Zadno-Azizi discloses the claimed structural elements of the device, thus, the device of Zadno-Azizi is capable of being implanted in a patient's vein for a period of one or more weeks and/or months. As to claims 21-24, Zadno-Azizi discloses the claimed structural elements of the device, thus, the device of Zadno-Azizi is capable of being adapted such that delivery of the fluid may be performed before, after, or during the inflation of the extension. As to claim 26, in Figure 11B, Zadno-Azizi show an aperture (328) which is covered by the extension

(318) in a first or deflated position. As to claim 27, the apertures in Figure 12 would be covered by the wall tissue of a patient's vein as the device is advanced in a deflated configuration through the narrow passages of the patient's body. As to claims 28-31, Zadno-Azizi discloses the tube comprising or having a material or fluid which is delivered into the particular portions of a patient's body which include fluids which are capable of preventing aggregation of solids, clot formation, body tissue inflammatory response, and bacteria colonization (see line 44 of column 13 to line 6 of column 14). As to claim 35, Zadno-Azizi teaches using an expansion fluid containing drugs which affect the formation of impediments (see lines 31-56 of column 13) and an expandable extension (422) which is permeable to the drugs (see line 44 of column 17 to line 22 of column 18). As to claims 44 and 45, Zadno-Azizi teaches that the device may be adapted for veins, arteries, and other locations in a patient's body and disclose the claimed structural elements of the device, thus, the device of Zadno-Azizi is capable of being adapted for an arm vein and fro an non-vein vessel. As to claims 46 and 47, at least a part of the extension is axially displaced when it is in the inflated position and at least a part of the extension is radially displaced when it is in the inflated position.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al in view of admitted prior art (admission). Kaplan et al disclose a device which is used in a patient's body and which is capable of dislodging an impediment. However, Kaplan et al are silent on the specifics of the impediment being a venous valve. Admission discloses numerous impediments or blockages which may be present in a patient's body including a vein valve, a regularly occurring part of the body's vein system, which may block an aperture of a inserted catheter or tube (see lines 5-13 of page 2 of applicant's specification). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device of Kaplan et al to dislodge or unblock a venous valve as taught by Admission as a venous valve is a well known form of blockage that can occur in the patient's body.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Herweck et al (U.S. Patent No. 6,955,661) disclose a tube with apertures and an expandable extension. Turner (U.S. Patent No. 5,638,812) and Samson et al (U.S. Patent No. 6,547,760) disclose coatings for catheters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER